accorded patentable weight.

I. Rejection Under 35 U.S.C. § 102 based upon U.S. Patent No. 5,691,370.

In Paper No. 7, the Examiner has rejected claims 1-4, 9-14, 20 and 22 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,691,370 of Cupps, *et al.* ("Cupps"). As basis for this rejection, the Examiner argues that Cupps discloses a pharmaceutical composition comprising terfenadine or terfenadine carboxylate, in combination with carriers and suspending agents and for use in intranasal and intraocular dosage forms. The applicants respectfully traverse this rejection.

To anticipate an invention, the reference must teach each element of the invention as claimed. Cupps fails this test. The invention is a composition consisting essentially of fexofenadine or its salt and a specific pharmaceutical excipient and/or is a composition comprising a specific quantity of fexofenadine and a specific pharmaceutical excipient. In contrast, the invention of Cupps is a composition containing certain substituted 5-(2-imidazolinyl amino)benzimidazole compounds that are alpha adrenoceptor agonists in combination with other active agents, such as terfenadine, and numerous carriers and excipients, such as sugars, polysaccharides, wetting agents, emulsifiers, stabilizers, antioxidants, and preservatives. Cupps teaches an appropriate dosage of terfenadine, if a composition containing terfenadine is to be administered to a patient, but does not teach or suggest the amount of terfenadine present in the 5-(2-imidazolinylamino) benzimidazole composition.

Accordingly, for at least the reasons given above, Cupps does not claim each element of the invention, and therefore does not anticipate it.

II. Rejection Under 35 U.S.C. § 102(e) over U.S. Patent No. 6,120,803 of Wong, et al.

At page 3 of Paper No. 7, the Examiner has rejected claims 1-3, 14, and 20 under 35 U.S.C. § 102(e) as being anticipated over U.S. Patent No. 6,120,803 of Wong, *et al.* ("Wong"). As basis for the rejection, the Examiner states that Wong teaches a composition comprising fexofenadine and a carrier. The Examiner makes the conclusory statement that "any excipient would have the ability to increase the solubility of fexofenadine or its salt in water because the generic claim recites excipient." However, the Examiner does not provide any support for this statement. The applicants respectfully traverse the rejection.

Wong discloses an active agent dosage form adapted for retention in the stomach of a human patient, and therefore useful in the prolonged delivery of an active agent formulation to a fluid environment. The Wong active agent dosage form is a solid capsule having a diameter of 7 mm to < 13 mm. The capsule is made of a polymer matrix and is structurally designed so as to swell upon contact with the water. A portion of the swellable polymer matrix of Wong is surrounded by a band of insoluble material that prevents the protected portion of the polymer matrix from contact with the fluid, and therefore from swelling. Wong teaches that the insoluble band permits the capsule to withstand the muscular contractions of the stomach, and thereby remain in the stomach until all of the active agent has been released from the swellable polymer matrix. Wong discloses a lengthy list of active agents that may be dispersed in the swellable polymer matrix, among which is listed fexofenadine. Additionally, Wong teaches that the dosage form may include non-polymeric water soluble excipients.

Wong does not teach each element of the invention. Wong does not teach a pharmaceutical excipient that increases the solubility of fexofenadine or the salt of fexofenadine in water. No disclosure of such excipients is provided in Wong at column 6 (where excipients are disclosed), nor is there any indication that it would be desirable to select excipients that act to increase the solubility of fexofenadine or its salts. The Examiner seems to be asserting that the characterization of the excipient described in the invention is a "intended use" and is therefore accorded no patentable weight. However, this is incorrect. The carrier of the invention is not, as the Examiner contends, "any" carrier, but includes those carriers that have a specific property. *See, for example,* the specification at pages 3-4.

Additionally, Wong does not teach a composition adapted for delivery of fexofenadine or a pharmaceutically acceptable salt to the eye or nose. Wong teaches a composition in the form of a banded capsule, which must be immersed in liquid for a long period of time in order for the fexofenadine to be released from the composition. Wong teaches that such compositions are for oral administration, not a suitable dosage form for intranasal or intraocular use.

Accordingly, for at least the reasons given above, Wong does not teach or suggest each element of the invention and therefore does not anticipate it. Reconsideration and withdrawal of the rejection are earnestly requested.

III. ***Rejection Under 35 U.S.C. § 102(e) based upon U.S. Patent No. 6,027,746.***

At pages 4-5 of Paper No. 7, the Examiner has rejected claims 1-3, 12-14 and 20 under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 6,027,746 of Lech ("Lech"). The Examiner argues that Lech discloses a composition containing fexofenadine and generic excipients, such as sorbitol, glycerine, corn syrup, sugar, alcohols, and mixtures thereof. The applicants respectfully traverse the rejection.

Lech teaches a pharmaceutical delivery system comprising a chewy, soft gelatin capsule within which a drug adsorbate is disbursed in a solid or liquid fill material. Lech teaches a list of suitable drugs for use in the chewy capsules, including fexofenadine. The drug incorporated into the chewy capsule is adsorbed onto the flake-like particles of an adsorbate, such as magnesium trisilicate or silicate dioxide. The drug is adsorbed to the flake-like adsorbate materials, to prevent it from dissolving into the liquid or solid excipient. This drug adsorbate complex is critical to Lech; because the active agent is prevented from dissolving, the patient does not taste it when the capsule is administered orally. Suitable aqueous-based film materials for use in the capsule include water, combined with a second excipient which, according to Lech, may be sorbitol, glycerine, corn syrup, sugar, alcohols, or mixtures of such substances.

Lech does not teach each element of the invention as claimed. First, Lech does not teach a pharmaceutical excipient that increases the solubility of the fexofenadine in water. There is no discussion or description in Lech of any efforts to increase or solubilize the fexofenadine in water or any other solvent. In fact, the composition of Lech is expressly directed to avoiding the solubility of the fexofenadine. Thus, Lech does not teach a pharmaceutical excipient that increases the solubility of fexofenadine in water.

Accordingly, for at least the reasons given above, it is submitted that Lech fails to teach each element of the invention as claimed and reconsideration and withdrawal of the rejection based upon Lech are respectfully requested.

IV. ***Rejection Under 37 C.F.R. § 102(e) based upon U.S. Patent No. 6,177,452.***

At page 5 of Paper No. 7, the Examiner has rejected claims 1-4, 12-14, and 20 under 35 U.S.C. § 102(e) asserting that such claims are anticipated by U.S. Patent No. 6,117,452 of Ahlegren ("Ahlegren"). Specifically, the Examiner argues that the "future intended use is not critical in a composition claim" and Ahlegren discloses a composition comprising fexofenadine,

excipients and surfactants. The applicants respectfully traverse this rejection.

Ahlegren does not teach each element of the invention as claimed. Again, the applicants point out that the Examiner has failed to consider that the excipients of the claimed invention include only those excipients that increase the solubility of fexofenadine in water. Ahlegren, in contrast with the present invention, teaches excipients that are water-insoluble, and therefore, would necessarily not serve to increase the solubility of fexofenadine in water. The use of water-insoluble excipients, such as glyceryl monostearate, which, by virtue of their water-insolubility are structurally unable to enhance the solubility of fexofenadine in water, does not meet the elements of the invention as claimed. Accordingly, for at least the reasons set forth above, it is respectfully submitted that Ahlegren does not teach each element of the claimed invention. Therefore, it does not anticipate the invention as claimed and reconsideration and withdrawal of the rejection based upon Ahlegren is respectfully requested.

V. Rejection Under 35 U.S.C. § 102(a) based upon the Physician's Desk Reference (pp. 1189-1190)(1998).

At pages 5-6 of Paper No. 7, the Examiner has rejected claims 1-3, 9-11, 14, 20, and 22 under 35 U.S.C. §102(a) as being anticipated by the cited portion of the Physician's Desk Reference ("PDR"). Specifically, the Examiner asserts the PDR discloses a capsule dosage form of fexofenadine (Allegra™) which comprises excipients and other additives such as iron oxide, gelatin, silicon dioxide, titanium dioxide, and sodium laurel sulfate. The Examiner asserts that "the route of administration is not critical in a composition claim and what the excipient does is not critical in a composition claim." The applicants respectfully traverse the rejection.

The PDR discloses capsules containing 60 mg of fexofenadine hydrochloride and specific excipients that are croscamellose sodium, gelatin, lactose, microcrystalline cellulose, and pregelatinized starch. The outer shell of the PDR capsule contains iron oxide gelatin, gelatin, silicon dioxide, titanium dioxide, and sodium lauryl sulfate. The active agent is not dissolved in or incorporated into the outer shell compounds.

The composition disclosed in the PDR does not teach each element as claimed. First, the composition of the PDR is a solid dosage form that is clearly not adapted for administration to the eye or nose. The PDR composition is in a form for oral administration. Further, none of the excipients used in the capsules of the PDR act to increase the solubility of

fexofenadine in water. In contrast, the present invention requires that the excipients utilized in the composition are those that increase the solubility of fexofenadine in water.

Accordingly, for at least the reasons set forth above, it is respectfully submitted that the PDR does not teach or suggest each element of the claimed invention, and is not anticipatory of it. It is respectfully requested that the Examiner reconsider and withdraw her § 102 rejection based upon the PDR.

CONCLUSION

In view of the foregoing, it is submitted that all pending claims are fully distinguished over the cited prior art of record. Accordingly, the applicants respectfully request reconsideration and withdrawal of the Examiner's rejections.

Respectfully submitted,

LISBETH ILLUM *et al.*

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KRISTYNE A. BULLOCK
Registration No. 42,371
AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P.
One Commerce Square
2005 Market Street, Suite 2200
Philadelphia, PA 19103
Telephone: (215) 965-1200
Direct Dial: (215) 965-1348
Facsimile: (215) 965-1210
E-Mail: kbullock@akingump.com

WWS/KAB/vj

Enclosures

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Marked-Up Version of Claim 1

U.S. Patent Application No. 09/834,312

Shown below are the changes to claim 1 marked up to show the changes made. Please note that deletions are indicated by brackets and insertions are indicated by underlining.

1. (Amended) A composition [comprising] consisting essentially of (i) fexofenadine or a pharmaceutically acceptable salt thereof and (ii) a pharmaceutical excipient which increases the solubility of the fexofenadine or salt in water, which is adapted for delivery of the fexofenadine or pharmaceutically acceptable salt thereof to the eye or nose.